

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMACEUTICALS L.P., and
RHODES TECHNOLOGIES,

Plaintiffs,

v.

VARAM, INC. and KVK-TECH, INC.

Defendants.

Civ. Action No. 10-cv-6038 (SHS)

Civ. Action No. 11-cv-0766 (SHS)

Civ. Action No. 12-cv-2814 (SHS)

Civ. Action No. 12-cv-6047 (SHS)

Oral Argument Requested

**STATEMENT OF MATERIAL FACTS IN SUPPORT OF VARAM, INC.'S
SUMMARY JUDGMENT MOTION OF NON-INFRINGEMENT
OF THE THREE CHAPMAN PATENTS**

There are no genuine issues of material fact concerning the underlying basis for this motion. The facts are as follows:

1. Three of the four patents-in-suit are the Three Chapman Patents, each of which shares a specification that is the same for all purposes of this motion. Exhibit 1 (collection of the ‘799, ‘800 and ‘072 patents).

2. Purdue is asserting that Varam infringes the following “asserted claims”: claims 3 and 19 of the ‘799 patent, claims 1, 19-21, 23-24, 26, 30-34, 57, 67-68, 70, 73, 74, and 76-79 of the ‘800 patent, and claims 1, 4, and 5 of the ‘072 patent.

3. Each of the asserted claims contains language directed to the compound 14-HC. The language requires that certain amounts of 14-HC be found in oxycodone salt (“14-HC amount language”) and that at least a portion of the 14-HC be derived or converted in a process from another compound, “8 α ” (*i.e.*, 8 α ,14-dihydroxy-7,8-dihydrocodeinone) (“14-HC derivation process language”). Each of the asserted claims has these requirements of the 14-HC, either explicitly or because it is a dependent claim that references a claim with the element. Exhibit 2 (chart highlighting the 14-HC amount language in yellow and the 14-HC derivation process language in red in the asserted claims).

4. The further narrowing and defining of the 14-HC of the claims, that is found in the 14-HC derivation process language, was added to the claims to attempt to overcome prior art rejections (*i.e.*, Chiu and Oshlack) being advanced by the Examiner. Exhibit 3 (Plaintiffs’ statements in the prosecution history); Exhibit 4 (Plaintiffs’ position on the prosecution history, which Varam adopts for purposes of this motion only (§ 82)). Plaintiffs also contend that this limitation of the 14-HC derivation process language was added to the claims because of the Proksa reference. Exhibit 4 (§ 85 (“Casner introduced Proksa ... Purdue had [] opportunity to

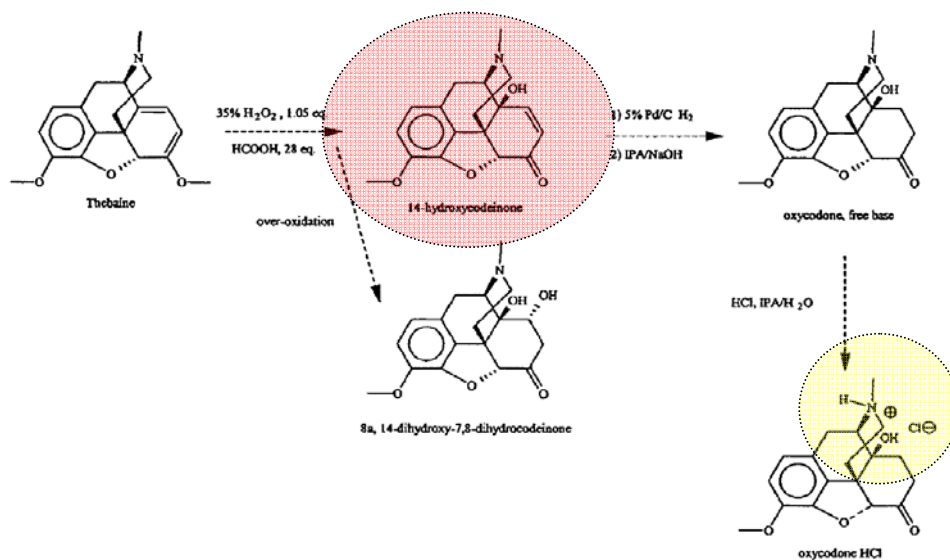
present claims that specifically recited 8 α . Purdue did so ... and the additional limitation that 14-hydroxy was derived from 8 α ” was added to the claims)). This added language was accompanied by arguments and the Baldwin Declaration. Exhibit 4 (§ 86); Exhibit 5 (April 22, 2008 Responses). The Examiner allowed each of the three patents to issue because of the amendment, the arguments, and the Baldwin Declaration. Exhibit 4 (§§ 86-96); Exhibit 6.

5. It was known in the literature that 14-HC can be converted to a different compound, 14-hydroxycodeinone hydrochloride (“14-HC hydrochloride”), through a reaction sequence (Exhibit 7, Ramanathan, p. 350):

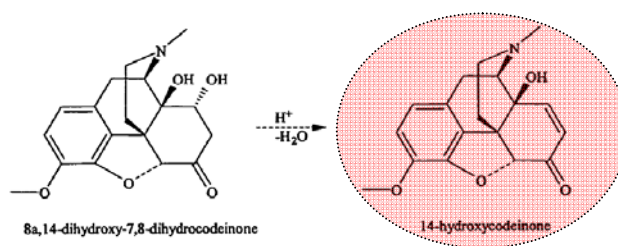
“*14-Hydroxydihydrocodeinone* – The unpurified 14-hydroxycodeinone was converted to its hydrochloride (m.p., 282-3°; lit. m.p., 285-6°C.) by dissolving the base in strong hydrochloric acid, cooling and recrystallizing from boiling water.” [footnote omitted.]

6. Thus, 14-HC is a different molecular and chemical entity than 14-HC hydrochloride (e.g., different formulas and chemical names; different melting points found by Ramanathan (270-1°C versus 282-3°C) and reported in the literature cited by Ramanathan (275-6°C versus 285-6°C)). Exhibit 7 (14-HC and its melting point are described on page 350 just above the description of the 14-HC hydrochloride manufacture)). Ramanathan is highly analogous prior art because it concerns the manufacture and purification of oxycodone (which it refers to as its alternative name, 14-hydroxydihydrocodeinone), which is the same subject matter as the Three Chapman Patents. *Id.*

7. Figures 1 and 2 of the specification of the Three Chapman Patents each define 14-HC very clearly with the chemical structure shown. This structure shown is the structure for 14-HC. It is not the structure for 14-HC hydrochloride. Exhibit 1 (compare the structure of 14-HC, highlighted in red with the relevant portion of oxycodone hydrochloride, highlighted in yellow).

FIGURE 1

Reaction scheme of the process used to produce oxycodone HCl from thebaine.

FIGURE 2

Dehydration of 8α, 14-dihydroxy-7,8-dihydrocodeinone

8. 14-HC hydrochloride is never mentioned in the specifications of the Three Chapman Patents or in any of their parent applications. It is also never mentioned in the prosecution of the Three Chapman Patents. In contrast, 14-HC is mentioned throughout the specification and the prosecution history of the Three Chapman Patents and it is focus of the alleged invention.

9. Plaintiffs have not and cannot adduce any evidence that the Varam accused products use oxycodone hydrochloride that contains 14-HC. Instead, they contain 14-HC hydrochloride, a different compound.

10. 14-HC hydrochloride cannot be considered the equivalent of 14-HC because it is a different compound with different properties (e.g., different structure and different melting points) (§§ 5-8, *supra*) and because of the narrowing definition of 14-HC added to the claims with the 14-HC derivation process language (§ 4, *supra*).

Dated: October 18, 2012

Respectfully submitted,

By: /s/ Donald L. Rhoads

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CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of the preceding document has been caused to be served via ECF on at least the following counsel of record for Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies this 18th day of October, 2012:

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